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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,722	12/10/2004	Peter Neu	00143-00244-US	6059

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CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
ARNOLD, ERNST V	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/517,722	NEU ET AL.	
	Examiner	Art Unit	
	Ernst V. Arnold	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-5,7-11 and 13-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-5,7-11 and 13-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/10/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges receipt of remarks filed on 5/18/2006. Applicants arguments have been fully considered. Applicant's amendments have necessitated new grounds of rejection. Applicant has cancelled claims 1, 6, and 12. Accordingly, claims 2-5, 7-11 and 13-17 are pending in the application.

Withdrawn rejections:

1. Claim 1 has been cancelled so the rejection under 35 U.S.C. § 101 is moot.

2. Claims 7-11 were rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. Applicant has amended the claims to overcome this rejection and the rejection is withdrawn.

3. Claims 7 and 9-11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended the claims to overcome the 35 U.S.C. 112, second paragraph, rejection and the rejection is withdrawn.

4. Claims 1-2 and 9-11 were rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434). Fishman does not teach the instant methods and the rejection is withdrawn.

5. Claims 1-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Briend et al. (US 5,670,177) and Briend et al. (WO 97/15311). Applicant has amended the claims to overcome the rejection and the Examiner withdraws the rejection.

6. Claims 1-44 have been cancelled in copending application 10/380,869 in an amendment filed on 6/6/2006 thus making the provisional double patenting rejection over instant claims 1 and 2 moot.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 15 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of therapy of impairments of cognitive performance, also postoperatively, does not reasonably provide enablement for the prophylaxis of impairments of cognitive performance, also postoperatively. Please note that the Examiner interprets prophylaxis to mean prevention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims without an undue amount of experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or

direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification merely discloses, without more, that a method of administering a gaseous mixture to patients. However, Applicant is purporting prophylaxis of impairments of cognitive performance, also postoperatively.

2) Nature of the invention

The nature of the invention is directed to a methods of administering a gaseous mixture comprising xenon.

3) Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like and laboratory technicians with Masters and Bachelors degrees as well as high school interns.

4) State of, or the amount of knowledge in, the prior art

The art teaches methods of administering xenon gas for the treatment of neurointoxications (Petzelt et al. WO 00/53192).

5) Level or degree of predictability, or a lack thereof, in the art

A high degree of unpredictability existed in the state of the prior art regarding the prophylaxis of cognitive impairments. There is no known cure for Parkinson's disease (Medical Encylopedia: Parkinson's Disease, page 3 of 5). There is no known cure for multiple sclerosis (Medical Encylopedia: Multiple Sclerosis, page 3 of 4).

6) Amount of guidance or direction provided by the inventor

Applicant was required to provide in the specification additional guidance and direction with respect to how use the claimed subject matter in order for the application to be enabled with respect to the full scope of the claimed invention. Although the instant specification discloses a composition and method of administering the composition to, it remains silent on the prophylaxis of impairments of cognitive performance, also postoperatively.

7) Presence or absence of working examples

The specification fails to provide scientific data and working embodiments with respect to a method of prophylaxis of impairments of cognitive performance, also postoperatively.

8) Quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure

As a result, one of ordinary skill in the art would be required to conduct an undue amount of experimentation to reasonably and accurately determine whether the

corresponding method of the instant application does in fact provide prophylaxis of impairments of cognitive performance, also postoperatively.

In conclusion, it is readily apparent from the aforementioned disclosure, in conjunction with a corresponding lack of scientific data and working embodiments regarding the prophylaxis of impairments of cognitive performance, also postoperatively, that one of ordinary skill in the art would therefore be required to conduct an undue amount of experimentation to reasonably and accurately extrapolate whether said method does in fact provide prophylaxis of impairments of cognitive performance, also postoperatively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-5, 8-11 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-5, 8-11 and 15-17 are dependent on a cancelled base claim (claim 12) and it is unclear to the Examiner the metes and bounds of these claims. For purposes of Examination, the Examiner will examine the claims as if they were dependent from the only independent claim 7.

Claims 7, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant amended the claim to recite:

"...wherein what is administered...". It is unclear to the Examiner what "what" is. The Examiner suggests replacing "what" with "gas mixture" which finds support in the line immediately above. The claim will be interpreted in this way for purposes of examination. Claims 13 and 14 are rejected as being indefinite because they are dependent on an indefinite base claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 7, 13, and 15-17 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Petzelt et al. (WO 00/53192).

Petzelt et al. disclose preparations and methods of use of xenon or xenon gas mixtures for treating neurointoxications (a chronic cerebral disorder such as Parkinson's disease) in a therapeutically useful concentration (Page 5, paragraph 1; page 11, paragraph 4 and claims 1, 7 and 16, for example). The preparation can have a ratio of xenon to oxygen of 80 to 20 percent by volume thus reading on instant claims 1-3 (Page 8, second paragraph and claims 15 and 17). Administration is by simple inhalation (Page 12, line 1). Methods of mixing the gases are provided (Page 8, paragraphs 3 and 4). Methods of administration are also provided (Page 9, paragraphs 1 and 2).

Response to arguments:

Applicant asserted that the prior art practices do not include as a step the selecting as a patient some one having the specified condition and then administering the xenon spasmolytic to that patient to treat the condition. The Examiner respectfully disagrees. Petzelt et al. teaches, for example, treating someone with Parkinson's disease or craniocerebral trauma or ischemia (thus identifying the patient population) and then administering a gaseous mixture most preferably 75-70:25-30 % by volume xenon:oxygen mixture to that patient thus reading on instant claim 17 (Page 7, last paragraph - page 8, first two paragraphs). The Examiner interprets a patient with Parkinson's disease to have spasms and impairment of cognitive performance thus reading on instant claims 15 and 16.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 2-4, 6, 7, 9 and 12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 4-7 of copending Application No. 10/10/517,723. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 2 and copending claim 2 are drawn to therapeutically effective amounts of xenon. Instant claim 4 comprises a spasmolytic and xenon, which makes obvious copending claim 4 composition comprising xenon and a NO source. NO is a spasmolytic. Copending claim 5 and instant claims 2 and 3 are drawn to therapeutically effective amounts of NO and xenon. Copending claim 6 and instant claim 7 are drawn to the use of the xenon and where appropriate NO source. Copending claim 7 and instant claims 9 and 12 are drawn to the use of xenon and where appropriate an NO source for the therapy or prophylaxis of impairments of cognitive performance.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

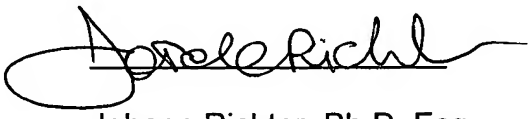
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616



Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600